

DIN EN ISO 11138-7:2019-11 (E)

Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results (ISO 11138-7:2019)

Contents

Page

European foreword	4
11.7 Sterility assurance level calculation	29
11.8 Test equipment	29
12 Culture conditions	30
12.1 General	30
12.2 Incubation temperature	30
12.3 Incubation period	30
12.4 Choice of growth medium	31
13 Third-party considerations	31
13.1 General	31
13.2 Minimum requirements from ISO 11138-1 for replicates and total number of biological indicators	32
13.3 Test equipment	32
14 Personnel training	32
15 Storage and handling	33
16 Disposal of biological indicators	33
Annex A (informative) Microbiological inactivation kinetics and enumeration techniques	34
Annex B (informative) Process challenge devices	39
Annex C (informative) Formulae for D value determination by fraction-negative method	40
Annex D (informative) Examples of documentation for biological indicators prepared by the user ...	56
Annex E (informative) Calculation of z value	60
Annex F (informative) D value determination by survivor curve method	63
Annex G (informative) Survival-kill response characteristics	67
Bibliography	69
11.5 F(T, z) equivalent sterilization value determination	28
11.6 Establishing spore-log-reduction	28